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February 27, 2015

1027487

Documents Processing Desk – 6(a)(2)
U.S. Environmental Protection Agency
Office of Pesticides Programs
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: FIFRA Section 6(a)(2) Report
Ceva Animal Health, LLC – Company Number 83399

Dear Sir/Madam:

Enclosed is a copy of the 4th~~3rd~~ Quarter (Oct-Dec) 2014 summary report for Ceva Animal Health, LLC for the following product registrations:

- SVP-7 Vectra 3D and SimpleGuard3, EPA Registration No. 83399-6; also sub-registered as First Shield Trio, EPA Registration No. 83399-6-85581
- SVP-8 Vectra for Cats, Vectra for Cats and Kittens, and SimpleGuard for Cats and Kittens, EPA Registration No. 83399-9; also sub-registered as First Shield for Cats, EPA Registration No. 83399-9-85581
- SVP-9 Vectra for Dogs and Puppies, EPA Registration No. 83399-10; also sub-registered as First Shield Dog and Puppy, EPA Registration No. 83399-10-85581

We trust this information satisfies EPA FIFRA Section 6(a)(2) reporting requirements. Please contact me by phone at 913-754-7668 or by e-mail at alicia.henk@ceva.com if additional information is required.

Sincerely,

Alicia Henk
Director,
Development and Pharmaceutical Regulatory Affairs

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FIFRA 6(a)(2) Adverse Effects Reporting Aggregate Report Form

FIFRA 6 (a)(2) Aggregate Adverse Effect Information Submission Form

Period Covered: 4th Quarter (Oct-Dec) 2014

Submission Date: February 27, 2015

EPA Reg. No.: 83399-6

Page: 1 of 2

Product Name: Vectra 3D for Dogs

Active Ingredients: Dinotefuran, Pyriproxyfen, Permethrin

-001

Total Incidents	Exposure Types and Severity Category Designations						
	H-D	H-E	D-A	D-B	D-C	D-D	D-E
287	19	0	2 ^A	0	21	243	2

ADDITIONAL INFORMATION:

^A Notes for D-A:

2014-US-002867: On 06 Oct 14, "Cece" a 4 year(s) old, 55 pound(s), intact, female, German Shepherd in good condition was administered Vectra 3D 21-55# (lot #: unknown, single dose) topically by the owner for the first time. On 06 Oct 14 the animal exhibited agitation and pruritus in an unspecified amount of time post application. There were no treatments administered. On 20 Oct 14 the animal died of unknown causes. The animal was never examined by a veterinarian or administered any treatments when the first clinical signs were noted. There were no diagnostic tests ran and there was no necropsy performed. No further information is expected. Case is closed.

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Period Covered: 4th Quarter (Oct-Dec) 2014

Submission Date: February 27, 2015

EPA Reg. No.: 83399-12

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Product Name: Vectra Pro Flea Spray

Active Ingredients: Dinotefuran

-002

Total Incidents	Exposure Types and Severity Category Designations						
	H-D	H-E	D-A	D-B	D-C	D-D	D-E
0	0	0	0	0	0	0	0

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Period Covered: 4th Quarter (Oct-Dec) 2014

Submission Date: February 27, 2015

EPA Reg. No.: 83399-10

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Product Name: Vectra for Dogs and Puppies

Active Ingredients: Dinotefuran, Pyriproxyfen

-003

Total Incidents	Exposure Types and Severity Category Designations						
	H-D	H-E	D-A	D-B	D-C	D-D	D-E
5	1	0	0	0	0	4	0

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-004

Period Covered: 4th Quarter (Oct-Dec) 2014

Submission Date: February 27, 2015

EPA Reg. No.: 83399-9

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Product Name: Vectra for Cats/ Vectra for Cats and Kittens

Active Ingredients: Dinotefuran, Pyriproxyfen

Total Incidents	Exposure Types and Severity Category Designations						
	H-D	H-E	D-A	D-B	D-C	D-D	D-E
36	3	0	1 ^A	0	3	28	1

^A Notes for D-A:

2014-US-002987: On 07 Aug 14, "Rosie" (20yr, 5.9 lb, f/s, Domestic Short Hair Cat) in poor health, with a extensive history of weight loss, elevated kidney values, and anemia, had Vectra for cat and kittens less than 9 lb (3pk, lot # unspecified) applied via spot method, by the pet owner. This product had been applied previous months without any problems. On 08 Aug 14, the owner found the cat deceased. The veterinarian suspects kidney disease, hyperthyroidism, and hypertrophy cardiomyopathy as diagnoses. There was no necropsy performed. The attending veterinarian's opinion regarding this event is that it is unlikely the product was causal. Additionally, the animal's medical history could have contributed to the reported clinical signs. Case is medically closed.

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- 075

Period Covered: 4th Quarter (Oct-Dec) 2014

Submission Date: February 27, 2015

EPA Reg. No.: 83399-10-85581

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Product Name: First Shield for Dogs and Puppies

Active Ingredients: Dinotefuran, Pyriproxyfen

Total Incidents	Exposure Types and Severity Category Designations						
	H-D	H-E	D-A	D-B	D-C	D-D	D-E
4	0	0	0	0	1	3	0

FIFRA 6(a)(2) Adverse Effects Reporting Aggregate Report Form

FIFRA 6 (a)(2) Aggregate Adverse Effect Information Submission Form

-006

Period Covered: 4th Quarter (Oct-Dec) 2014

Submission Date: February 27, 2015

EPA Reg. No.: 83399-9-85581

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Product Name: FirstShield for Cats/ FirstShield for Cats and Kittens

Active Ingredients: Dinotefuran, Pyriproxyfen

Total Incidents	Exposure Types and Severity Category Designations						
	H-D	H-E	D-A	D-B	D-C	D-D	D-E
4	0	0	0	0	1	3	0

FIFRA 6(a)(2) Adverse Effects Reporting Aggregate Report Form

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Period Covered: 4th Quarter (Oct-Dec) 2014

Submission Date: February 27, 2015

EPA Reg. No.: 83399-6-85581

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- 009

Product Name: First Shield Trio for Dogs

Active Ingredients: Dinotefuran, Pyriproxyfen, Permethrin

Total Incidents	Exposure Types and Severity Category Designations						
	H-D	H-E	D-A	D-B	D-C	D-D	D-E
39	5	0	1 ^A	0	4	29	0

^A Notes for D-A:

2014-US-002858: On 04 Oct 14, the pet owner purchased First Shield for Cats over 9 lb (4pk), but was dispensed First Shield Trio for Dogs 2.5-20# (lot #ANP, 4 pk) by the animal hospital. On 04 Oct 14, "Black Nose" (outdoor only cat, unknown breed, sex, and age) was applied First Shield Trio for Canine 2.5-20 lb (lot #ANP, 4pk) by the pet owner unknowingly. This was an off label use of the product. Immediately after the application, the cat was acting strange and ran away. The owner was advised by the veterinarian to bathe the cat with Dawn dish soap and bring the cat in to the hospital for further treatment. The owner was unable to locate the cat. On 21 Oct 14, the owner called to report the cat was found deceased (date unspecified). No necropsy was performed. Cats are very sensitive to permethrin. Adverse signs expected are tremors, ataxia, depression, vomiting, seizures, and death. Case is medically closed.

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Period Covered: 4th Quarter (Oct-Dec) 2014

Submission Date: February 27, 2015

EPA Reg. No.: 83399-6

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-008

Product Name: SimpleGuard 3for Dogs

Active Ingredients: Dinotefuran, Pyriproxyfen, Permethrin

Total Incidents	Exposure Types and Severity Category Designations						
	H-D	H-E	D-A ^A	D-B	D-C	D-D	D-E
34	4	0	1	0	3	26	0

^A Notes for D-A:

2014-US-003220: On 02 Dec 14, Pearl (Feline, 9 yr, 9.8lb, M/N, DSH) had SimpleGuard 3 2.5-20lb (Lot #ANP, Unspecified package) applied topically by the owner on accident, as the product is labeled for dogs. It is unspecified if the cat has had the product previously, or if there were any products administered concurrently. On 04 Dec 14, two days post application the cat developed facial twitching, hyperthermia, hypothermia, and tachycardia. The cat was presented to the attending veterinarian where it was bathed in LDWD, and Midazolam (1cc) was administered. The tremors continued into seizures. On 08 Dec 14, four days post application the cat was euthanized due to no improvement in the clinical signs. There was no necropsy performed. Cats do not tolerate permethrin. Cats that are exposed and not properly treated can succumb to the clinical signs. Case is medically closed.

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Period Covered: 4th Quarter (Oct-Dec) 2014

Submission Date: February 27, 2015

EPA Reg. No.: 83399-9

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Product Name: SimpleGuard for Cats

Active Ingredients: Dinotefuran, Pyriproxyfen

Total Incidents	Exposure Types and Severity Category Designations						
	H-D	H-E	D-A	D-B	D-C	D-D	D-E
4	1	0	0	0	0	3	0